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Treatment Manual

Certifying Facilities

Certification of Irradiation Treatment Facilities

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Introduction

To be authorized to apply approved phytosanitary irradiation treatments, an irradiation facility shall obtain a Certificate of Approval from USDA, and either into a binding Compliance Agreement with USDA and/or the official national plant protection organization (NPPO) in the country where located.

In general, approved facilities must be able to demonstrate that their equipment and personnel are able to deliver the minimum dose, safely, accurately, and consistently, to all components of the commodity, over the range of conditions expected for commodities treated. In addition, USDA may consider characteristics of each facility in assessing the degree to which unique physical and process specifications are necessary to ensure adequate safeguarding. The requirements for irradiation facility approval for overseas facilities shall be equivalent to those applied to facilities located in the United States. All approved facilities must agree, as part of the certification process, to immediately notify USDA of any problems, concerns, or irregularities in commodity treatments. USDA or its NPPO counterpart may conduct periodic quality assurance and operational scrutiny.

Certification Requirements

To receive a Certificate of Approval to treat commodities to mitigate regulated pests in commodities, the facility shall satisfactorily comply with the following five key elements described in this section:

1. Current Licence
2. Minimum Dosage
3. Biological Safeguards
4. Documented Training
5. Documented Procedures

Current Licence

The facility must be currently licensed by all relevant State, or appropriate National regulatory authorities.

Minimum Dosage

The facility must be capable of administering at least the minimum required absorbed ionizing radiation dose, as prescribed by USDA for the particular pest complex/commodity to be treated.

Biological Safeguards

The facility must be constructed so as to provide physical separation of untreated and treated commodities, ensuring biological security. If mobile pests (such as adult fruit flies) are the target, the commodity shall be in pest-proof containers or separated by a wall or by a screen with a mesh size fine enough to exclude flying insects. Retrofitting an established facility with a screen barrier or wall may not be a practical option. USDA may waive this requirement if one or more of the following three conditions apply:

- ◆ The irradiation facility is located in an area that would not support an infestation of the target pests
- ◆ The pests of concern are immobile
- ◆ The commodity to be irradiated arrives at the facility in pest-containment cartons.



In all such cases, a physical separation of treated and untreated product is still necessary, and may consist (at the minimum) of a barrier sufficient to prohibit inadvertent movement of commodities, wherein commingling of treated and untreated products might occur.

Documented Training

Document the training of key employees on the operation of an irradiation processing facility, applicable to irradiation treatment of agricultural products. All personnel with treatment-related responsibilities shall have proper credentials, training, and authority for application of irradiation treatments. Appropriate records shall be made available for inspection by USDA officials, and/or by officials of the corresponding national plant protection organization, on request.

Documented Procedures

The irradiation facility shall be required to have well documented standard operating procedures (SOPs) defining the processing, handling, and safeguarding of regulated agricultural commodities. The SOPs shall be reviewed by the regulatory official during inspections, to ensure conformance to the Compliance Agreement, applicable treatment schedule(s), and other applicable regulations.



For the purpose of expediency, the manager of the facility is advised to submit a letter to the certifying official, specifically addressing how the facility proposes to comply with the safeguards that will become part of the Compliance Agreement. (see Safeguarding Irradiation Treatment Facilities, [page-3-3-12.](#))

Request for Approval

The request package shall address the five key elements listed in the certification requirements section. Applicants requesting approval of an irradiation processing facility for mitigating regulated agricultural pests shall submit the request, in writing, to:



Oxford Plant Protection Laboratory
USDA, APHIS, PPO
901 Hillsboro Street
Oxford, NC 27565

The request should include a cover letter identifying the facility, operator, owner, and the individual who will be responsible for the Compliance Agreement. The latter person shall be physically located at the treatment facility and have full authority to ensure compliance with the conditions of the agreement. Attachments to the request should include a plan of the facility and an outline of the processes and procedures to be used by the facility to meet the requirements described above. This information shall be held in strict confidence.

Site Approval Visit

The certifying official(s) from USDA shall review all documents for completeness, and correspond with the applicant, as needed. When all documents have been approved, an official site approval visit will be scheduled. During this visit, the certifying official shall compare the floor plan schematic and product flow pattern with the actual installation, review the safeguards that are in place, and conduct an audit of treatment records (if any). The site approval visit may include

a representative from the host country's national plant protection organization (NPPO), if applicable, and may also include officials from other interested regulatory agencies.



Following certification, the facility manager shall agree that USDA and/or NPPO officials may make spot checks from time to time at the facility. These visits may be either announced or unannounced.

Certificate of Approval

Upon approval of the facility, USDA shall issue a Certificate of Approval (PPQ form 482), outlining the terms, conditions, and restrictions of the approval. This certificate shall remain valid for one year unless revoked or withdrawn. Recertification shall be required annually, or whenever reinstatement is requested. Recertification shall not be required except in such cases where reinstatement is requested. The USDA approval status of all irradiation treatment facilities, both domestic and foreign, that apply treatments to mitigate regulated agricultural pests shall be tracked by:



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